IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Russell Heinrich et al.	Examiner:	Darwin P. Erezo
Serial No.:	10/510,869	Group:	Art Unit 3773
Filed:	October 7, 2004	Dated:	March 19, 2009

For: **METHOD AND APPARATUS FOR ANASTOMOSIS INCLUDING AN EXPANDABLE ANCHOR**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-4150

AMENDMENT

Sir:

In response to the final Office Action dated January 21, 2009 regarding the above-identified application, please consider the following amendment and remarks:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper;

Remarks/Arguments begin on page 11 of this paper.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: **March 19, 2009**

Megan Stopek

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Previously presented) A device for joining a first body vessel to a second body vessel, comprising:

an inner member having a distal end portion and defining a longitudinal axis;

an outer member defining a lumen dimensioned to receive the inner member therein;

a radially expandable anchor disposed at the distal end of the inner member, the expandable anchor having an initial condition wherein the expandable anchor is disposed between the outer member and the inner member and an expanded condition; and

a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition.

2. (Original) The device according to claim 1, wherein the expandable anchor is made from at least one of a sponge-like and a foam-like material.

3. (Original) The device according to claim 2, wherein the expandable anchor has a frusto-conical shape when in the expanded condition.

4. (Original) The device according to claim 3, wherein a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor when in the expanded condition.

5. (Original) The device according to claim 2, wherein the expandable anchor radially expands upon contact with moisture.

6. (Original) The device according to claim 1, wherein the inner member comprises an inner tubular sleeve defining a central lumen extending therethrough.

7. (Original) The device according to claim 6, wherein the inner tubular sleeve includes a region near its distal end which is porous to permit transmission of moisture, via the central lumen, to the expandable anchor.

8. (Original) The device according to claim 6, wherein the expandable anchor is arranged, when in the expanded condition, to permit liquid to pass therethrough and drain through the inner tubular sleeve.

9. (Original) The device according to claim 1, wherein the expandable anchor defines at least one longitudinally oriented passage extending completely therethrough when in the expanded condition.

10. (Original) The device according to claim 1, further comprising a control unit, remotely located, for operating the anastomotic device.

11. (Cancelled).

12. (Original) The device according to claim 1, further comprising a grasper operatively connected to the distal end of the inner tubular sleeve.

13. (Original) The device according to claim 2, wherein the expandable anchor is fabricated from a bio-absorbable material.

14. (Original) The device according to claim 13, wherein the material dissolves after a predetermined period of time.

15. (Previously presented) A device for performing a surgical anastomosis of a first body vessel and a second body vessel, comprising:

a pair of concentric tubular sleeves including an outer sleeve and an inner sleeve, each of the pair of concentric tubular sleeves having a distal end portion and a proximal end portion; and

a radially expandable anchor operatively disposable between the distal end portions of the pair of concentric tubular sleeves, the radially expandable anchor including a proximal end portion configured for exerting a first radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a second radially outward force on the

other of the first and second body vessels, the first radially outward force being different from the second radially outward force.

16. (Original) The device according to claim 15, wherein the expandable anchor is fabricated from at least one of a foam-like and sponge-like material.

17. (Original) The device according to claim 16, wherein the expandable anchor has an initial condition for insertion of the anastomotic device through a body lumen and an expanded condition which inhibits withdrawal of the anastomotic device from the body lumen.

18. (Original) The device according to claim 17, wherein the expandable anchor is expanded from the initial condition to the expanded condition by application of a fluid.

19. (Original) The device according to claim 17, wherein the expandable anchor has a frusto-conical shape when in the expanded condition.

20. (Original) The device according to claim 17, wherein the expandable anchor has a thin-walled cylindrical shape when in the initial condition.

21. (Original) The device according to claim 17, wherein the expandable anchor defines at least one longitudinally oriented passage extending entirely therethrough when in the expanded condition.

22. (Original) The device according to claim 17, wherein the inner tubular sleeve of the pair of concentric tubular sleeves includes a region of porosity formed near the distal end thereof.

23. (Original) The device according to claim 22, wherein the region of porosity to transmit a fluid to the expandable anchor.

24. (Original) The device according to claim 23, wherein the inner tubular sleeve includes at least one longitudinally oriented lumen extending therethrough, wherein the lumen is configured and adapted to transmit the fluid to the plurality of perforations.

25. (Original) The device according to claim 16, wherein the expandable anchor is fabricated from a bio-absorbable material.

26. (Withdrawn) A method of performing a surgical anastomosis, comprising the steps of:

providing a device for performing the surgical anastomosis, the device including:

a member having a distal end portion;

a radially expandable anchor operatively disposed at the distal end portion of the member; and

a cover disposed over the radially expandable anchor; and

passing the device through an opening in a first body vessel and into a second body vessel such that a distal end portion of the expandable anchor is positioned at least partially within the second body vessel;

withdrawing the cover to expose at least the distal end portion of expandable anchor;

expanding at least the distal end portion of the expandable anchor within the second body vessel such that the expandable anchor engages the second body vessel;

moving the device until the second body vessel contacts a distal end of the first body vessel and a proximal end portion of the expandable anchor is positioned at least partially within the distal end of the fist body vessel;

withdrawing the cover to expose the proximal end portion of the expandable anchor; and

expanding the proximal end portion of the expandable anchor within the distal end of the first body vessel such that the expandable anchor engages the distal end of the first body vessel.

27. (Withdrawn) The method according to claim 26, wherein the steps of expanding include the introduction of a fluid to the expandable anchor.

28. (Withdrawn) The method according to claim 26, wherein the expandable anchor is fabricated from at least one of a foam-like and sponge-like material.

29. (Withdrawn) The method according to claim 28, wherein the expandable anchor is expanded by application of liquid thereto.

30. (Withdrawn) The method according to claim 29, wherein the expandable anchor has a frusto-conical shape when in an expanded condition.

31. (Withdrawn) The method according to claim 29, wherein the expandable anchor has a thin-walled cylindrical shape when in a compressed condition.

32. (Withdrawn) The method according to claim 29, wherein the member comprises an inner tubular sleeve having a region of porosity formed near the distal end thereof and the liquid is introduced through the sleeve, through the region of porosity, to the expandable anchor.

33. (Withdrawn) The method according to claim 26, wherein the step of moving comprises approximating a body organ and a body lumen.

34. (Withdrawn) An anchoring device, comprising:

a member having a distal end;

a radially expandable anchor disposed at the distal end of the member; and

a cover disposed over the radially expandable anchor to maintain the radially expandable member in an initial pre-expanded condition.

35. (Withdrawn) The anchoring device of claim 34, wherein the cover comprises a tubular sleeve having a lumen sized to receive the member and the radially expandable anchor.

36. (Withdrawn) The anchoring device of claim 34, wherein the radially expandable anchor is sized so that upon removal of the cover, the anchor expands.

37. (Withdrawn) The anchoring device of claim 34, wherein the radially expandable anchor comprises a sponge that radially expands upon the introduction of a fluid.

38. (Withdrawn) A method of deploying an anchoring device, comprising:

providing an expandable anchor, the expandable anchor being expandable upon introduction of a fluid;

introducing the fluid to a first portion of the expandable anchor so that the first portion is expanded and a second portion of the expandable anchor remains in the pre-expanded configuration; and

introducing the fluid to the second portion of the expandable anchor so that the second portion is expanded.

39. (Withdrawn) The method of claim 38, wherein the expandable anchor comprises a sponge and the fluid comprises a liquid.

40. (Withdrawn) The method of claim 38, wherein the expandable anchor comprises a membrane expanded upon introduction of the fluid.

41. (Withdrawn) The method of claim 38, wherein the first portion engages a body vessel upon expansion.

42. (Withdrawn) The method of claim 41, further comprising the step of moving the expandable anchor, after the first portion is expanded, so that a second body vessel is adjacent the second portion.

43. (Withdrawn) The method of claim 42, wherein the second portion engages the second body vessel upon expansion.

44. (Previously presented) The device according to claim 15, wherein the radially expandable anchor is configured for exerting a radially outward force on an inner surface of the first and second body vessels along substantially the entire length of the radially expandable anchor.

REMARKS/ARGUMENTS

The present application has been reviewed in light of the Office Action dated January 21, 2007. Applicant respectfully traverses the rejection of claims 1-10, and 12-44. It is respectfully submitted that claims 1-10, and 12-44 are fully supported by the specification, introduce no new matter, and are allowable over the cited art of record. Prompt and favorable consideration of these claims is earnestly sought.

Claims 26-43 were withdrawn from consideration, without prejudice, as they were not elected in response to a restriction requirement. Claim 11 was previously cancelled.

In the Office Action, claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21, and 44 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,176,864 to Chapman (hereinafter "Chapman").

Pursuant to 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. Applicant respectfully submits that Chapman fails to disclose each and every element recited in independent claims 1 or 15, as required by 35 U.S.C. § 102.

According to the Office Action, Chapman discloses "a device for joining a first body vessel to a second body vessel (anastomosis device), comprising: a concentric inner member 20 having a distal end portion and defining a longitudinal axis; a concentric outer member 40 defining a lumen dimensioned to receive the inner member therein; and a radially expandable anchor 30 disposed at the distal end of the inner member, the expandable anchor having an initial

condition wherein the expandable anchor is disposed between the outer member and the inner member (Fig. 4) and an expanded condition; and a sheath (everted portion of graft member 10) located at the distal end of the expandable member for defining a shape of the expandable anchor in the expanded condition such that a distal end of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition(see Fig. 9)."

Nowhere does Chapman disclose each and every limitation of independent claim 1, including a device for joining a first body vessel to a second body vessel including, *inter alia*, an expandable anchor having "a sheath disposed about [an] expandable anchor for defining the shape of the expandable anchor when in [an] expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition"

Chapman discloses an anastomosis device for coupling an end of a graft vessel to a side of a target vessel. The anastomosis device includes a tubular member 20 and a radially compressible graft coupling member 30. When performing an anastomosis using Chapman's device, a free end of the graft vessel 10 is inserted through an opening in a tubular member 20 and moved longitudinally within the tubular member until the free end of the graft vessel extends beyond the tubular member 20. The fastener and graft vessel are then inserted into an introducer 40 and the inner wall of the introducer 40 will radially compress the graft coupling member. As shown in Figures 3-7A, the graft extends beyond the tubular member where the free end of the graft vessel 10 may be everted over an end of the introducer 40 (FIG. 6) (column 6, lines 39-57).

Claim 1 recites, "a sheath disposed about [an] expandable anchor for defining the shape of the expandable anchor when in [an] expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the

expanded condition." As described in Applicant's specification, and in one embodiment illustrated in Figure 13, "the shape and configuration of anchor 214, in the expanded condition, is substantially bell-shaped or fluted," (paragraph [0084]). As supported in the specification and recited in claim 1, the distal end portion of the expandable anchor is radially larger than the proximal end portion. Conversely, the graft coupling member 30 of Chapman is "radially compressible", and as defined in the specification of Chapman by " 'radially compressible' it is meant that the graft coupling member 30 is generally uniformly radially transformable between a free, normal expanded state and one or more compressed states..." (column 5, lines 38-40). The graft coupling member 30 is compressible so that it can be inserted into the introducer 40. Furthermore, nothing in Chapman suggests that the graft vessel 10, with the introducer 40 overlying the graft coupling member 30, could define the shape of the graft coupling member 30. Chapman does not disclose or suggest a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition; Chapman illustrates (FIGS 1-15) and discloses a uniform radial transformation.

Applicant respectfully disagrees with the Office Action's characterization of the graft vessel 10 as a sheath. The words of a claim must be given their "plain meaning" unless such a meaning is inconsistent with the specification. During examination, The USPTO must give claims their broadest reasonable interpretation in light of the specification. "Plain meaning refers to the ordinary and customary meaning to a person of ordinary skill in the art." See MPEP section 2111.01.

> "The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary

> skill in the art in question at the time of the invention.....The ordinary and customary meaning of a term may be evidenced by a variety of sources,> including 'the words of the claims themselves, the remainder of the specification, the prosecution history, and the extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.' *<Phillips v. AWH Corp., *> 415 F3d at 1314<, 75 USPQ2d **> at 1327.*"

Claim 1 requires a sheath disposed about the expandable anchor for defining the shape of the expandable anchor. The sheath as described in the Applicant's specification includes, for example, (as depicted in FIG. 13) a sheath 270 which confines the anchor 214 to define a structural shape of the anchor 214. Sheath 270 provides a graduated proximal slope to facilitate positioning and alignment of the tissues to be joined as described in paragraph [0088]. In particular, sheath 270 may facilitate shaping of the anchor 214 such that anchor 214 may be configured for engagement with particular body vessels, such as bladder neck "N" and urethra "U" as described in paragraph [0097]. To interpret the graft vessel as the sheath 270 as suggested by the Office Action is contrary to both the plain meaning of the claim terms, as well as the teaching in the specification.

Furthermore, Chapman does not disclose or suggest a sheath disposed about an expandable anchor as defined in Claim 1. Chapman discloses a vessel graft which is longitudinally advanced through tubular member and everted. Furthermore, nowhere does Chapman disclose or suggest that the everted graft, or what the Office Action refers to as a sheath, defines the shape of the expandable anchor in the expanded position. In Chapman, the

graft coupling member 30 is compressed between the tubular member 20 and introducer 40 such that removing the introducer 40 permits the graft coupling member 30 to move to an expanded state (FIG 9). In the expanded state, the graft coupling member 30 is uniformly expanded within the everted end of the graft vessel 10 to "apply a gentle circumferentially uniform, radial pressure against the inverted graft vessel" (col. 7, lines 47-49). There is no disclosure or suggestion that the everted graft vessel confines the graft coupling member 30 to a structural shape as required by claim 1.

Therefore, it is respectfully requested that the rejection of claim 1 be withdrawn.

Claims 2, 4, 6, 8, 9, and 12 either directly or indirectly depend from claim 1 and incorporate all of the limitations of claim 1. For at least the reasons noted above with respect to claim 1, Applicant asserts that the dependent claims 2, 4, 6, 8, 9, and 12, are unanticipated by Chapman.

The Office action also rejected claim 15 under U.S.C. §102(b) as being anticipated by Chapman. According to the Office Action, Chapman discloses a device for joining a first body vessel to a second body vessel (anastomosis device), comprising: a pair of concentric tubular sleeves including an outer sleeve 40 and an inner sleeve 20, each of the pair of concentric tubular sleeves having a distal end portion and a proximal end portion; and a radially expandable anchor 30 operatively disposable between the distal end portions of the pair of concentric tubular sleeves, the radially expandable anchor including a proximal end portion and a distal end portion capable of providing a radially outward force when the anchor expands. The examiner also took the position that the radially expandable anchor of Chapman expands along its length, thus the proximal and distal portion of said expandable anchor will provide a radially outward force. The

examiner also notes that the first body vessel or the second body vessel are not positively recited in the claims.

Nowhere does Chapman disclose each and every limitation recited in claim 15, including "a device for performing a surgical anastomosis of a first body vessel and a second body vessel, comprising: a pair of concentric tubular sleeves including an outer sleeve and an inner sleeve, each of the pair of concentric tubular sleeves having a distal end portion and a proximal end portion; and a radially expandable anchor operatively disposable between the distal end portions of the pair of concentric tubular sleeves, the radially expandable anchor including a proximal end portion configured for exerting a first radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a second radially outward force on the other of the first and second body vessels, the first radially outward force being different from the second radially outward force." In one embodiment of the present application, a proximal end portion 114b of expandable anchor 114 extends into the urethra "U" and exerts a radially outward force thereupon (see paragraph [0072]). In contrast to claim 15, the proximal end of the graft coupling member 30 of Chapman extends out of the target vessel 12 and radially surrounds the graft vessel 10. [[except the portion that is everted over the device...]] Nothing in Chapman suggests different radially outward forces being exerted by the graft coupling member 30.

In view of the foregoing, Applicant respectfully submits that the structure described in independent claim 15 is not taught, disclosed or contemplated by Chapman or the prior art references of record. For at least the reasons discussed above, Applicant asserts that the rejection of claim 15 be withdrawn.

Claims 16, 17, 20, 21, and 44 depend directly or indirectly from claim 15 and incorporate all of the limitations of claim 15. For at least the reasons noted above with respect the claim 15,

Applicant asserts that dependent claims 16, 17, 20, 21, and 44 are unanticipated by the cited art and allowable over the cited art of record.

The Office Action then rejected claims 3 and 19 under U.S.C. 103(a) as being unpatentable over Chapman in view of U.S. Patent No. 2, 898, 913 to Ritter et al. (hereinafter "Ritter").

Ritter relates generally to a hemostatic cone for insertion into the fossal cavity to enhance the healing process following a prostatectomy (see col. 1, lines 15-20). Ritter fails to cure the deficiencies of Chapman no matter how the references may be combined. Ritter does not disclose or suggest each and every limitation of claim 1 including "a sheath disposed about [an] expandable anchor for defining the shape of [an] expandable anchor when in the expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition" as recited in independent claim 1. Also, Ritter does not disclose or suggest the deficiencies of Chapman including "radially expandable anchor including a proximal end portion configured for exerting a first radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a second radially outward force on the other of the first and second body vessels, the first radially outward force being different from the second radially outward force" as recited in independent claim 15.

Accordingly, in view of the foregoing, since Ritter fails to cure the deficiencies of Chapman, Applicant submits that claims 3 and 19 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Ritter. Therefore it is respectfully requested that the rejection of claims 3 and 19 be withdrawn.

The Office Action also rejected claims 5, 13, 14, 18, and 25 under U.S.C. 103(a) as being unpatentable over Chapman in view of U.S. Patent No. 5, 411, 520 to Nash et al. (hereinafter "Nash").

Nash relates generally to a system for sealing a percutaneous puncture in a blood vessel and discloses a collagen plug 30 that expands in the presence of blood (see col. 7, lines 1-4). Nash fails to cure the deficiencies of Chapman no matter how the references may be combined. Nash does not disclose or suggest "a sheath disposed about [an] expandable anchor for defining the shape of [an] expandable anchor when in the expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition" as recited in independent claim 1. Also, Nash does not disclose or suggest a radially expandable anchor including a proximal end portion "configured for exerting a first radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a second radially outward force on the other of the first and second body vessels, the first radially outward force being different from the second radially outward force" as recited in independent claim 15.

Accordingly, in view of the foregoing, since Nash fails to cure the deficiencies of Chapman, Applicant submits that claims 5, 13, 14, 18 and 25 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Nash. Therefore it is respectfully requested that the rejection of claims 5, 13, 14, 18, and 25 be withdrawn.

The Office Action also rejected claims 7 and 22-24 under U.S.C. 103(a) as being unpatentable over Chapman in view of U.S. Patent No. 6, 241, 743 to Levin et al. (hereinafter "Levin").

Levin fails to cure the deficiencies of Chapman no matter how the references may be combined. Levin relates generally to a device for creating an end to side anastomosis having a generally tubular structural member 12 (see col. 4, line 64) with a porous region 26 (see col. 5, lines 63-67). Levin does not disclose or suggest "a sheath disposed about [an] expandable anchor for defining the shape of the expandable anchor when in the expanded condition such that a distal end portion of [an] expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition" as recited in independent claim 1. Levin also fails to disclose a radially expandable anchor including a proximal end portion "configured for exerting a first radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a second radially outward force on the other of the first and second body vessels, the first radially outward force being different from the second radially outward force " as recited in independent claim 15.

Accordingly, in view of the foregoing, since Levin fails to cure the deficiencies of Chapman, Applicant submits that claims 7 and 22-24 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Levin. Therefore it is respectfully requested that the rejection of claims 7 and 22-24 be withdrawn.

The Office Action also rejected claim 10 under U.S.C. 102(b) as being anticipated by or, in the alternative, under U.S.C. 103(a) as obvious over Chapman. Claim 10 recites "a control unit, remotely located, for operating the anastomotic device."

Applicant submits that claim 10 is allowable under both 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) over Chapman in view of the amendments and remarks presented above with regard to claim 1. Claim 10 depends from claim 1, and since, as discussed above, Chapman fails to disclose or suggest each and every limitation of independent claim 1, including an expandable

anchor having "a sheath disposed about [an] expandable anchor for defining the shape of [an] expandable anchor when in the expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition." As discussed above, Chapman does not disclose the sheath, as claimed. Applicant respectfully submits that the subject matter of claim 10 as a whole is patentable over Chapman.

It is respectfully requested that the rejection of claim 10 be withdrawn.

In view of the foregoing, it is respectfully submitted that all claims presently pending in the application, namely claims 1-10, and 12-25, and 44 are in condition for allowance. Should the Examiner believe that a telephone or personal interview may facilitate resolution of any remaining matters, the Examiner is respectfully requested to contact the Applicant at the telephone number indicated below.

If any fee is due in connection with this response, the examiner is authorized to charge deposit account number 210550 therefor.

Respectfully submitted,

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